PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 11/00, 15/00, 16/00, B05D 7/14, B65D 83/06	A1	(11) International Publication Number: WO 95/07723
		(43) International Publication Date: 23 March 1995 (23.03.95)

(21) International Application Number: PCT/US94/10310

(22) International Filing Date: 14 September 1994 (14.09.94)

(30) Priority Data:
08/122,128 16 September 1993 (16.09.93) US

(71) Applicant: MEDTRAC TECHNOLOGIES INC. [US/US]; Suite 115, 12364 Alameda Parkway, Lakewood, CO 80228 (US).

(72) Inventors: WOLF, James, L.; 12 Sand Cherry Street, Littleton, CO 80121 (US). SALLIS, Daniel, V.; 5720 Blue Sage Drive, Littleton, CO 80123 (US).

(74) Agent: CRABTREE, Edwin, H.; Suite 575, 3773 Cherry Creek N. Drive, Denver, CO 80209 (US).

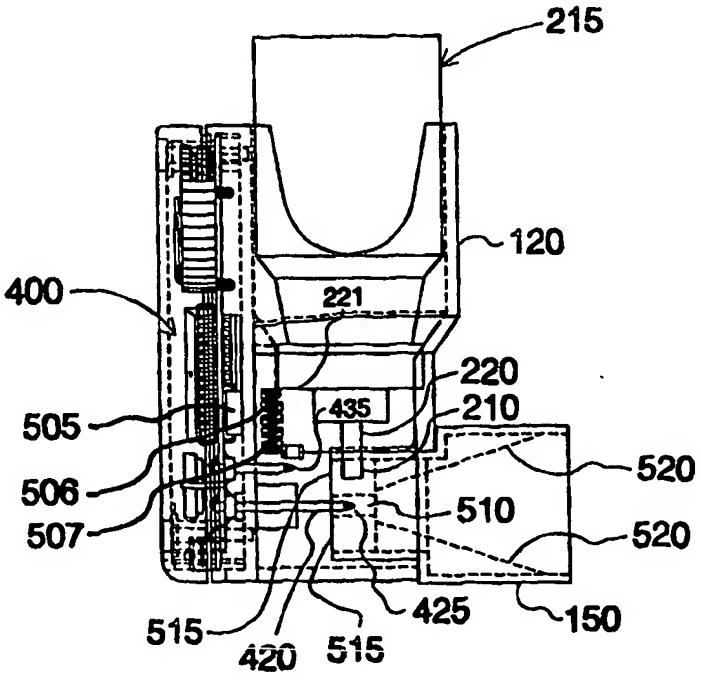
(81) Designated States: European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: INHALER HAVING AN ATTACHABLE DOSING MONITOR AND RECORDER

(57) Abstract

This invention is a medication inhalant device (100) for use with an attachment to a conventional pressurized canister (215) for monitoring prescribed dosages of medication. The device includes an electronic package (400) for computing and recording the amount and duration of each dosage of medication dispensed from the canister. A fast response temperature thermistor (425) is used for sensing the amount and duration of the inhalant released. The device also includes an ambient air flow sensor (435).



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgystan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo			SE	Sweden
CH	Switzerland	KR	Republic of Korea	SI	Slovenia
CI	Côte d'Ivoire	KZ	Kazakhstan	SK	Slovakia
CM	Cameroon	LI	Liechtenstein	SN	Senegal
CN	China	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
CZ	Czech Republic	LV	Latvia	TJ	Tajikistan
DE	Germany	MC	Monaco	TT	Trinidad and Tobago
DK	Denmark	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali	UZ	Uzbekistan
FR	France	MN	Mongolia	VN	Viet Nam
GA	Gabon				

INHALER HAVING AN ATTACHABLE DOSING MONITOR AND RECORDER

TECHNICAL FIELD

The present invention relates to the field of medication monitoring and, more particularly, to a device which attaches to conventional medication delivery systems, such as asthmatic medication pressurized inhalant canisters, for positive recording of prescribed dosages and system to analyze chronologic report.

BACKGROUND OF THE INVENTION

The medical drug industry has come a long way in developing "miracle" wonder drugs in the last century. Patients benefit, in many cases, to complete recovery from diseases that were once fatal when contacted. With today's sophisticated super drugs, one expects success with such treatment.

However, success is greatly determined by the diligence of medication at prescribed dosages and administered in timely manner. When patients are in hospitals, diligent dispensing of medication is certainly practiced, but even in hospitals there is no positive log of such medication dispensing. In out-patients, the diligence of following the prescribed schedules is dramatically diminished. Often the patient or family member is forgetful and exact times of medication are missed, totally forgotten or proper dosages are erroneous.

Unfortunately, patients are not getting the full benefit of prescribed drugs because exact adherence to critical dispensing schedules and dosage amounts are not being reliably accounted for. Doctors are, at best, guessing the patient has followed mediation instructions completely, and are making vital decisions accordingly.

The present invention is not related to improving medication dispensing devices, but rather sets forth a device for attaching to existing medication dispensers to

more properly control the amount, time and even remind the user of a scheduled dosage. It is a portable unit highly miniaturized to fit within the grip of a closed hand. Doctors can program the desired dosage and schedule into the device along with the patient's name and the prescribed drug. The patient then attaches the prescribed drug in its manufacture's dispenser package, to the apparatus. The apparatus shall then remind the patient when to take the medication. The apparatus logs the exact time and date of each usage as well as an indication of the appropriate dosage. The patient may change out depleted drug dispenser packages as needed and replace with new ones. The apparatus of the present invention even records this event.

On the next scheduled appointment with the patient's doctor, The apparatus is connected to a retrieval device for "up-loading" the recorded events. From this data, a full accountability of prescribed drug usage is listed. Graphic representations of the periodic dispensing of medication is positively registered. The doctor can now make critical judgment calls based on exact information as to; interval, missed scheduled medications, "strength" of medication. In the prior issued patent entitled "Timed Pill Monitor and Dispenser", U.S. Patent No. 4,662,537, issued on May 5, 1987 to the present inventor, a medication monitor was disclosed wherein pre-packaged medication "pills" were placed into compartmental chambers on a hand held device for later usage. Such a system is useful for recording the event of each time a chamber was accessed and a pill removed for prescribed medication.

The present invention provides a positive registration that a medicated inhalant has been properly dispensed and logged.

Prior to the filing of this application, the subject inventors conducted a patentability investigation for a system that monitors the administration of prescribed drugs, and provides a chronological report for all activity therewith. The following patents in addition to

the above stated patent were uncovered in the search:

Inventor	Reg. No.	Date
Kehr et al.	5,200,891	Apr. 6, 1993
Johnson, IV et al.	5,133,343	Jul. 28,1992
Wood et al.	5,097,429	Mar. 17,1992
Moulding	5,042,685	Aug. 27, 1991
Foley	5,042,467	Aug. 27, 1991
Moulding	4,869,352	Sep. 26, 1989
Behl	4,473,884	Sep. 25, 1984
Moulding	4,460,106	Jul. 17, 1984

Discussion of discovered prior art:

The patent issued to Kehr et al (U.S. Letters Patent No. 5,200,891) pertains to a device having a plurality of compartments, each of which store medication pills and an electrical signaling system to emit medication alert signals. The disclosed signals indicate that medication should be taken, from which compartment and the quantity. The device of Kehr has a high degree of inter-action between the user and its operation by selecting push-buttons and reading messages on the device display.

In the apparatus of Johnson, IV et al. (U.S. Letters Patent No. 5,133,343) has a user's mouthpiece housed therein an automatically actuated commercially available and replaceable inhalers for discharging a medicated vapor. The primary objective of Johnson, IV invention is to provide a device for actuating an inhaler in response to inhalation by a user.

In the 1992 patent issued to Wood et al. (U.S. Letters Patent No. 5,097,429) pertains to a user programmable microprocessor based apparatus which acts as a reminder to a medication schedule of events. When user programs parameters relating to intervals of medication, the device prompts the user by signaling alarm.

The third patent of Moulding (U.S. Letters Patent No.) 5,042,685, Aug. 27, 1991) manages the dispensing of pills. While the second patent of Moulding (U.S. Letters Patent No. 4,869,352, Sep. 26, 1989) pertains to conforming to the shape and size of pill for dispensing,

and Moulding's July 17, 1984 patent (U.S. Letter Patent No. 4,460,106) concerns the counting of pills being dispensed.

In the Foley patent (U.S. Letters Patent No. 5,042,467) teaches improved misting of inhaler medication which provides warning by means of sonic signalling if the user inhales too vigorously.

In the 1984 patent issued to Behl (U.S. Letters Patent No. 4,473,884) sets forth an electronically controlled medication dispenser with a second pharmacy programmer used to program the dispenser. The dispenser includes a plurality of compartments for storage of tablets or pills. Each compartment has associated indicators which activate and are announced audibly, first softly, and then increasingly in magnitude to a programmed time schedule. The user would then open indicated compartment an take the suggested dosage of medication. The pharmacy desktop sized programmer may program the electronic dispenser to optimize the medication schedule with user's personal eating and sleeping habits. Such information is programmed into a non-volatile memory within.

None of the above approaches discloses an approach for chronologically recording dispensed medication as a matter of fact, positively registering and logging all event. Many of the devices have push-buttons associated with the apparatus to program schedules that essentially function as a reminder with no positive action that medication has been taken. Of the dispensing electronic apparatuses, they pertain to "pill" or "tablet" form of medication. The inhalant related patents provide assistance to the user in the administration of the inhalant medication.

DISCLOSURE OF THE INVENTION

An object of the present invention is to provide a portable, highly miniaturized device which when attached to a conventional medication inhalant dispenser packaging

positively monitors the administration of the medication.

Another object of the invention is the device includes a sensor placed in the approximate path of the inhalant and the medicated inhalant and the magnitude of the inhalant as it is being dispensed is sensed. The output of the sensor is delivered into a circuit for determining the proper proportion of the medication and determines if the user has positively received the medication.

Still another object of the inhalant device is the electronic package of the invention makes a record of the event including the exact time and date and a determining circuit of the package is capable of giving a warning to the patient that something less then a proper dosage has been dispensed so a second actuation of the inhalant may be administered, or the conventional medication dispenser package can be replaced with a new one.

Yet another object of the invention is the electronic medication metered dosage inhaler can be periodically connected to a system by a Doctor's office, hospital, and like medical facilities to up-load stored information and analyze the chronologic report stored within. This may be accomplish directly or through a telephone and a modem.

The medication inhalant device adapted for receiving a conventional pressurized canister in a hand held housing and for monitoring prescribed dosages of medication received through the lips and into the mouth, throat, and respiratory system of a user of the device includes an electronic package received in the housing for computing and recording the amount and duration of each dosage of medication dispensed from a valve stem of the canister. The housing includes an upper chamber for slidably receiving and holding the canister therein, a lower chamber, and an air inlet. One end of a removable mouthpiece is slidably received inside the lower chamber of the housing with the user's lips received around a portion of an exterior circumference of an opposite end of the mouthpiece. A fast response temperature thermistor is

mounted adjacent the valve stem received inside the mouthpiece. The temperature thermistor is disposed in a path of flow of the inhalant for sensing the amount and duration of the inhalant released. Also, an ambient air flow thermistor is disposed adjacent the air inlet for sensing the amount of air flow received in the lower chamber, through the mouthpiece, and into the user's mouth. The two thermistors generate signals to the electronic package. The signals are computed and recorded so that a doctor and patient can positively determine if the amount and duration of each dosage over a period of time is being properly inhaled for improved patient health care.

These and other objects of the present invention will become apparent to those skilled in the art from the following detailed description, showing the contemplated novel construction, combination, and elements as herein described, and more particularly defined by the appended claims, it being understood that changes in the precise embodiments to the herein disclosed invention are meant to be included as coming within the scope of the claims, except insofar as they may be precluded by the prior art.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings illustrate complete preferred embodiments of the present invention according to the best modes presently devised for the practical application of the principles thereof, and in which:

FIGURE 1 sets forth a perspective view of present invention.

FIGURE 2 is a side planar view of the device of the present invention with detachable mouthpiece separated from main body, and showing a conventional medication inhalant package.

FIGURE 3 is a cross-sectional view showing the inner chambers of the present invention.

FIGURE 4 is a side planar view of the electronics assembly and sensing elements of the present invention.

FIGURE 4a is a cross-sectional view showing detail of electronic main sensing element shown in Figure 4.

FIGURE 5 is a side planar illustration showing the device of FIGURE 2 and FIGURE 4 fully assembled.

FIGURE 6 is a rear planar view of the present invention with access cover removed to reveal battery placement.

FIGURE 6a is a front planar view showing inhalant sensing chamber with precision orifice.

FIGURE 6b is a rear planar view of the device of the present invention.

FIGURE 7 is a bottom planar view of the device of the present invention.

FIGURE 7a is a bottom planar view illustrating the sliding communications connector access panel in the open position.

FIGURE 8 is a schematic block diagram of the electronics of the present invention.

FIGURE 9 sets forth a state table for the control circuit of Figure 8.

FIGURE 10 sets forth an illustration of the system of the present invention being connected to a data retrieval device.

FIGURE 11 sets forth a rear exploded perspective illustration of a second embodiment showing an information display of the device of the present invention.

BEST MODE FOR CARRYING OUT INVENTION & INDUSTRIAL APPLICABILITY

In Figure 1 is shown an electronic inhalant device 100 of the present invention suitable for dispensing medicated inhalant in metered dosages. The body housing 120 which is only slightly bigger then and is familiar to a conventional inhalant dispenser having no capability to record events associated with the dispensing of the medication. This miniaturized and familiar feeling body 120 has disposed on the front, a replaceable mouthpiece 150. Conventionally available medicated inhalant canister

package would be placed in opening 130 as prescribed by a doctor. The medicated inhalant would pass through opening 140 of mouthpiece when unit is activated.

In Figure 2, the replaceable mouthpiece 150 is shown detached from body housing 120. This feature is to allow for the selection of an appropriate inhalant orifice size or to replace with a new mouthpiece for sanitary reasons. The surface 211 of replaceable mouthpiece 150 mates with receptive opening 212 of the body 120. The mouthpiece 150 would be pushed inward until fully seated at surface 213. Medication inlet 210 is then aligned so as to engage valve stem 220 of the medicated inhalant canister package 215. The medicated inhalant canister package 215 is any of a number of medications conventionally available.

When medicated inhalant canister package 215 is fully seated into body housing 120 so as to engage valve stem 220 with medication inlet 210, finger openings 205 expose the bottom portion 216 of canister 215. By holding canister 215 with thumb and forefinger at canister area 216 through finger opening 205, and pulling in the direction of arrow 217, removes medicant canister from device 100.

In Figure 3, the device 100 is shown in a side cross-sectional view revealing the inner chambers. Chamber 315 is the space which allows the medicated inhalant canister package 215 to be placed. Valve stem 220 and shoulder 221 fit snugly with inner surfaces 314 of chamber 315. There is an air inlet hole 316 which allows ambient air to flow in from opening 130 around sides of canister 215, through the device 100 when medication is being inhaled. This shall be discussed in detail late. Behind electronics access cover 200, is the electronics chamber 325. Orifice 320 allows the main sensing element 425 of Figure 4 to be substantially in the path of medication flow, and orifice 330 allows the air flow sensing element 435 to be in the ambient air inlet path.

In Figure 4 shows the electronics assembly 400 comprising electronic circuitry 405, batteries 410, and

411, communication connector 415, main sensing element 425, and air flow sensing element 435 all mounted on a single multi-layer printed circuit board 401. The main sensing element 425 is detailed in cross sectional Figure 4a whereupon a stainless steel support tube 420 is first press fitted to brass ferrule 430 and then affixed to printed circuit board 401 by means of a solder joint 431. The main sensing element 425 in the preferred embodiment is a fast response thermistor manufactured by Betatherm Corp, 910 Turnpike Rd., Shrewbury, MA 01545, as part No. 100K6MCA24. The thermistor is affixed to the stainless steel support tube 420 by means of thermally high conductive epoxy adhesive 427 with sensor wires 440 and 441 passing through hollow space 426 of tube 420, brass ferrule 430 and printed circuit board 401. These sensor wire leads are attached electrically to printed circuit board 401 at solder junction 442 and 443. Air flow sensing element thermistor is mounted similarly as sensor 425. It is to be expressly understood that any conventional sensing scheme using, for example a pressure device or an audio element device, could be used instead of the thermistor arrangement disclosed above and that the approach shown in Figure 4 and 4a is exemplary of one approach.

In Figure 5 discloses the present invention illustrated fully assembled. Proximity reed switch sensor 505 indicates to the microprocessor on the electronics assembly 400 that a medicated inhalant canister package 215 is in fact installed into the device 100. As the shoulder 221 of the canister 215 is inserted into position, a magnet 506 is pushed down onto a spring 507 and positioned within the operating field of the proximity reed switch sensor 505. By this means the device 100 knows and logs along with time and date, the number of medicant canisters which were used for any given prescribed period of time. The proximity reed switch sensor, magnet and spring are conventionally available and are commonly manufactured by several sources. The detail

of 505, 506 and 507 are not shown in Figure 5 but shall be disclosed more fully later.

The valve stem 220 which fits snugly into medication inlet 210 of Figure 2, when activated sprays inhalant medication into the inhalant sensing chamber 510 where sensor 425 of Figure 4 is substantially in the path. Coincidental to this action, which shall be more fully discussed later, the user inhales causing ambient air to enter through inlet 316 of Figure 3, monitored by air flow element 435 and proceeds through air passage slots 515. The medicated inhalant propelled spray is ejected through precision orifice, which shall be disclosed in Figure 6 as 650, and mixes with ambient air in space within dotted lines 520 as it is being expelled out mouthpiece opening 140. This process shall be discussed further in a later section of this disclosure.

Figure 6 shows the back side of the device 100 with the electronics access cover 200, as shown in Figure 6b, removed so as to reveal the electronics assembly 400. Threaded holes 630 hold the electronic assembly 400 and electronic access cover 200 in position using machined screws 670 which are receptive to threads in holes 630. A microprocessor 605 is shown on the assembly between the two battery systems 410 and 411. Batteries 410 are the main power to the device and are two conventional 3.0 volt lithium cells. The 3.0 volt battery 411 is to power the ram memory, on other side of printed circuit board not shown, if main batteries 410 are ever removed or become low in energy. Battery 411 provides non-volatility to date and time clock and ram circuitry. It is manufactured by Renata in Switzerland and available through Renata Batteries U.S., Dallas, Texas 75207, as part number CR927. This power system assures that all logged records are retained in the ram in the event the main power batteries 410 run down and need to be replaced. Battery clips 615 and 625 are provided to hold batteries 410 and 411 respectively in position.

In Figure 6a, the present invention shows within the

replaceable mouthpiece 150, the precision orifice 650, inhalant sensing chamber 510 and air passage slots 515. As discussed earlier, the orifice 650 of mouthpiece 150 is selectable by size as needed in various medication types, typically the diameter is 0.022 inches. This is accomplished by replacing the mouthpiece 150 as is appropriate and recommended be medication manufacturers.

In Figure 7 shows a communications access panel 680 in the closed position as integrated with body housing 120 and electronics access cover 200. By placing an object, such as a finger nail, in recess 705 and pushing, the panel 680 moves along guide and tracks 710 and 711 respectively as is shown in Figure 7a. Once panel 680 is fully open, the communication connector 415 is exposed and may be connect to for retrieval of captured chronology data which shall be discussed later.

In Figure 8 is disclosed a schematic block diagram of the electronic circuitry 405 on printed circuit board 401 of the electronic assembly 400. Main system battery 410 supplies a constant source of power to the input of 3 volt regulator 810 over regular source line 801. Main system battery power is also available to the inputs of electronic switches 840 and 845 over feed line 802. The output of 3 volt regulator 810 provides a constant source of standby power to all essential circuitry (the connections not shown) in addition to what is shown, connections to voltage reference(V Ref) 800 over line 811. The essential circuitry are components which initialize the process of detecting events and shall be discussed in detail later. The common terminal of proximity reed switch sensor 505 is also connected to V Ref 800 over line 811. Normally closed terminal of reed switch 505 is connected to canister"out" one-shot 830 over line 829 and further connected to microprocessor 605 I/O port. The normally open terminal of reed switch 505 is connected to canister "in" one shot 835 over line 834 and further connected to microprocessor 605 I/O port. The output of the one-shot 830 is connected to OR circuitry 875 input over line 831.

Likewise, the output of the one-shot 835 is connected to the OR circuitry 875 input over line 836. The output of OR circuitry 875, over line 839, is connected to control gate of electronic switch 840 and microprocessor 605 interrupt No. 1 (IR1) input. The output of electronic switch 840 is connected to the system voltage regulator 850 over line 841. The system voltage regulator 850 output provides operation power (Vcc) 805 to all circuitry (non standby) which has been shut off to conserve energy. Vcc 805 lines are not shown on this schematic block diagram. Once Vcc 805 has been brought up to power as the proceeding paragraphs shall detail, it is latched-on by instruction of the microprocessor as shall be discussed later in this section. To illustrate the function of the circuitry thus far, when medicated inhalant canister 215 is removed from electronic medicated inhalant chronology apparatus 100, magnet 506 moves in the direction of arrow 217 by means of spring 507 which releases the alternate action of proximity reed switch 505 to move to its normally closed position. This causes voltage available at input of reed switch 505 to be available on line 829 which functions one-shot 830 so as to provide a momentary pulse to the OR-ing circuitry 875, which in turn activates electronic switch 840 to provide Vcc power to the system for as long as the duration of the momentary pulse generated by one shot 830 (for example 100 milliseconds). Likewise, if a new medicated inhalant canister 215 is inserted into the electronic medicated inhalant chronology device 100, magnet 506 moves in the opposite direction of arrow 217 compressing spring 507. Magnet 506 effects proximity reed switch 505 to cause available standby power V Ref 800 to be on the normally open terminal providing power over line 834 to function one-shot 835. The momentary pulse output is over line 836 effect OR circuitry 875 and electronic switch 840 similarly to one-shot 830 as described earlier to provide system power Vcc 805. Further description of these functions shall be described later in the section. Lead 440 of fast response

thermistor 425 is also connected to V Ref 800 standby power over line 811. Thermistor 425 is further connected to input of differentiating amplifier 820 on lead 441. The input of differentiating amplifier 820 is also connected to "ground"potential through current limiting resister 815 over line 812. Differentiating amplifier 820 output is commonly connected to comparator 825 and microprocessor 605 analog to digital (A/D) converter 855 input by line 821. The function of amplifier 820 in part, is to "track" the slope of wave form 813. Comparator 825 outputs square waive signal 827 at threshold 881. The threshold 881 shall be discussed in detail later. Signal 827 is presented to the OR circuitry 875 and the microprocessor 605 I/O similarly as other 875 inputs as was described earlier, over common line 826. Again, the OR circuitry 875 functions to power the system Vcc 805 via electronic switch 840 and regulator 850, but in this case for the duration of pulse width 880. The clock and ram circuit 860 further functions to activate the OR circuitry 875 over line 857. Clock and ram circuitry 860 has its own independent standby power source battery 411. Battery 411 functions to operate the time and date clock at very low levels of energy in addition to maintaining stored data in the ram (random access memory) section of circuitry 860 during periods of main system power Vcc 805 shut-down, as will be fully discussed later. The clock and ram circuit 860 can be pre-programmed to cause a pulse on line 857. This pulse presented to the input of OR circuitry 875 functions to activate electronic switch 840 and system voltage regulator 850 providing power Vcc 805 similarly to functions previously described with one-shots 830 and 835, and comparator 825. All four of these circuits; 830, 835, 825, and 860 serve in part to activate electronic switch momentarily making system battery voltage available to system voltage regulator 850 which in turn activates main system power Vcc 805. Any time main system power Vcc 805 is activated all associated circuitry which was shut-down to conserve battery energy, comes

alive and functions according the rom (read only memory) program stored within microprocessor 605. Upon initialization of microprocessor 605, program instructions command electronic switch 845 to activate over line 844. System battery is now also provided to system voltage regulator 850 over line 842. The purpose of electronic switch 845 is to "latch ON" main system power Vcc 805 to all appropriate circuitry to function programmed instructions beyond the momentary pulsing activation interval generated at the output of OR circuitry 875 as was earlier described. The air sensing element thermistor 435 functions similar to the main sensor 425 except it is powered via Vcc 805 over line 833. Thermistor 435 is connected directly to A/D converter 855 through amplifier 885 over lines 884 and 887, with current limiting resistor 886 providing path to ground. During powering-up, the fast response thermistor element 435 self heats and when the ambient air passes through air inlet 316, would cause a drop in temperature. If no air is being drawn through ambient air inlet 316, the rate of temperature would continue to rise. The A/D converter 855 monitors these characteristics determining proper inhalation. Microprocessor 605 once initialized, responds to signals presented at its interrupt inputs IR1 and IR2. IR1 signal over common line 839 is indicative of activity generated by main sensing element 425 and proximity reed switch 505, the microprocessor 605 will scan I/O port to see which one of lines 829, 834, or 826 has toggled and shall proceed to predetermined programmed instructions based on which line is active. Additionally, when signal is present on line 826, microprocessor 605 activates function of its internal A/D converter 855 to be responsive to any signal present over line 821 and on line 887. The result of signals, and there characteristics, of 826, 821, 880, 881 and 882 are due to the activation of dispensing medicated inhalant and shall be more detailed later under the operations section of the present invention. The IR2 interrupt input of microprocessor 605 responds to activation generated from

the clock function of clock and ram circuit 860 over line 858. This interrupt is indicative of some predetermined programmed instruction, for example, "alarm" to take medication. Line 889 delivers informational data, instructions and alarm signals from microprocessor 605 to device 890 (which shall be further discussed in Figure 11 herein). Data and address lines 859 are conventionally connected between microprocessor 605 and clock and ram circuit 860, and functions as necessary according to conventional programming technique. Valid event LED (light emitting diode) indicator 865 illuminates when microprocessor 605 toggles output line 864. Current limiting resistor 870 functions to complete LED indicator 865 circuit. Illumination 866 serves as feedback to the user of the electronic inhalant device 100 when optional display/alarm device 890 is not present. It is understood that a tone generator could be substituted for an audible effect instead of the visual effect of the LED 865 circuit. Finally communications connector 415 is connected to the microprocessor 605 over by-directional transmit/receive line 838. Connecter 415 also provides external system power directly to system regulator 850 (not shown) when an external communications cable is connected to the electronic inhalant device 100 conserving battery life. This feature shall be further discussed in Figure 10. All components illustrated in schematical block diagram in Figure 8 are representative of functional components and are commonly available in a diversity of configurations by many manufacturers. Such components are easily connected to one another by anyone skilled in the art as set forth in the diagram of Figure 8. It is to be expressly noted that while individual sensor elements have been set forth and discussed for electronics shown in Figure 8, in the preferred embodiment, other sensor elements may be substituted to result in the same function. For example, thermistor sensors 425 and 435 which detects change in temperature as medicated inhalant passes in the approximate path creating wave form 813

could be produced by audio elements (and appropriate associated circuitry) detecting change of sound as medicated inhalant passes in the approximate path of sensor elements 425 and 435. The signature of the sound, both sonic and ultrasonic, created as the inhalant spray being, first passing through the inhalant sensing chamber 510 and, second expelling out of precision orifice 650 expanding and mixing with ambient air in the chamber 310 would have exact and repeatable characteristics. Or one further example, pressure or peizo sensors detecting changes in pressure as medicated inhalant passes in the approximate path of sensor elements 425 and 435 . These and other sensor element schemes all could be made to produce similar wave forms 813 and 827 and A/D signals present on lines 821 and 887, to provide input signals of the present invention. In Figure 9, is set forth the flow of logic in the form of a state table concerning the sensing elements for the operation of the electronic circuitry 405. This process is driven according to instruction program code conventionally written as executions recommended by components manufacturer data sheet recommendations for any desired result as may be capable of the component, and anyone skilled in the art could write such code.

In Figure 9, the following occurs. Power off state 900 normally exists in a standby mode. In the event an activity is sensed, such as a detected rate of temperature decrease of sensor 425, the power off state 900 enters the power on validate state 905 over path 901. It is in this state, that the electronic switch 840 activates system voltage regulation 850 to provide momentary Vcc 805 power to system to determine the validity of the activation.If the result of signals 826, 821, 880, and 881 (and their characteristics) meet the criteria wave forms 813 and 827 of Figure 8, indicating an activation of dispensing medicated inhalant, the log event state 910 is entered as valid over path 907. The event would be logged in memory complete with date and time, and magnitude of signal

present on line 821 indicating the strength of dosage being dispensed and magnitude of signal present on line 887 indication the airflow through ambient air inlet 316. If criteria wave form 813 and 827 are not the expectant shape and minimum threshold level 881, the system enters back to power off state 900 over path 906 and shut-down to a standby operation once again. It is important to understand that "validate signals" is part of the management of state 905 and as such determines if the activation of the device 100 expelling medicated inhalant is properly dispensed in user's mouth and respiratory system or otherwise expelled into surrounding ambient air.

From the log event state 910 the system enters into the flash LED/display/alarm state 915 over path 911 to provide feedback of the event to the user before entering back to the power off state 900 for standby shut-down over path 912. The flash LED/display/alarm state 915 may be entered directly from the standby 900 mode over path 902, as is in the case of clock and ram circuit 860 of Figure 8, would initialize upon a predetermined programmed schedule to remind user to take medication. It should be explicitly understood, that state 915 is symbolized as a general system configuration. It may be as simple as the LED indicator 865 or more complex as display 890 (which shall be elaborated in second embodiment of Figure 11 in detail), or may not exist at all. In the later case,path 912 would come directly from state 910 upon completion of logging event to return to standby power off 900. This later case is a zero feedback configuration which is desirable in "blind" testing patients to serve as medication dispensing behavior analysis.

Importantly, the teachings of the present invention provides feedback to the user as may be necessary. For example, device 100 having installed a placebo canister 215, is useful for helping new patients to get use to the timing in activation of the device and inhaling. The flash LED/display/alarm and sensor capability would indicate such feedback as; improper synchronization of

inhaling and inhalant release, inhaling too slow or too fast, and inhaling too hard or too soft. All events are monitored and logged.Once the new patient was comfortable with proper operations of self administering the inhalant, they could use a less complex display 890 configuration of the device 100.

To illustrate further the sensing elements and associated circuitry, the power on state 905 would be entered from standby power 900 over path 901 for each of the events indicated in time reference 882. Time 882 is a possible waveform indicating 3 valid recursive actuations of the electronic inhalant device 100. Note that each recovery peak 883a, 883b and 883c become less and less from the original starting temperature as is indicated at the start of time at wave form 882 of signal 813. By means of differentiating amplifier 820 in Figure 8, the threshold 881 is proportionally to each descending starting point of recursive activations 883b and 883c respectively. Wave form 827 of time 882 indicates that proper threshold criteria has been meet for each activation and would have entered power on validate state 905. This together with signals present on lines 821 and 887 as interpreted by A/D converted 855 would constitute a valid magnitude of signal indicating a proper dosage (or less than proper dosage as the case may be),whether or not inhalant was properly expelled into user's mouth, and log event in state 910. If less then full dosage is discerned, which would be indicated in the feedback flash LED/display/alarm state 915 (as may be possible when medicated inhalant canister package 215 is empty or near empty), would prompt user to actuate device 100 a second,or in the case of the above illustration a third time. For each of the three activations in the above illustrated example, the full cycle from powering up, validating signals,logging events, and as may be appropriate flashing LED or displaying or alarming, to power shut-down to standby would occur between each recursive activation because of the speed and efficiency

of electronics assembly 400. Similarly, when system activation is due to activity responsive to proximity reed switch sensor 505 (not shown in Figure 9), the power on validate state 905 would be entered and further enter state 910 to log event and give feedback of event in state 915. When communication connector 415 has been connected to external data retrieval device (disclosed in Figure 10),system enters into communication mode state 920 over path 903 and system becomes responsive to the external commands. The down-loading of possible entries would be; interval schedule of medication for auto alarm indication, quantity of dosage,type of medication, and patient's name. The up-loading function would extract all chronologically stored data including an instrument diagnostic report listing sensor behavior and battery supply voltage levels. These features shall be discussed further in the disclosure of the present invention in Figure 10, 11 and operation. The powering of system regulator 850 of Figure 8 is supplied directly from external source via connection to communication connector 415. Once disconnection from communication connector 415 happens, the communications mode state returns back to the power off state 900 and shuts-down to standby.

In Figure 10 the electronic inhalant device 100 has its communications access panel 680 in the open position and communications cable connector 1005 connected to matted receptacle 415 mounted on the electronics assembly 400 as identified in Figure 4. Communications cable 1010 and 1015 attach to computer 1020. The junction 1012 illustrates that communication modems may be in the data path transmission over cables 1010 and 1015 for remote retrieval of chronology stored records. Computer 1020 accesses the data base in the chronology device 100 for retrieval and analysis of the medication administered and is displayed in tabulated statistical form 1025 and graphically as in 1030. Such information may be stored in computer memory for combining with other similar chronology users data and further printed to hard copy

utilizing printer 1040. Keyboard 1035 is manipulated in conventional manner to program device 100 for scheduling if required by doctor. Retrieved information 1025 and 1030 also could represent a diagnostic report of the device 100 over the full recorded period of time which includes battery and sensor response. This information,under analysis, indicates if the instrument was functioning properly. The computer, printer, cabling and connectors are all conventional and well known and are easily operable by anyone skilled in data handling. The emphasis here is that positive reporting of prescribed medication is diligently recorded and analyzed to assure the benefits of the medicine doing what the doctor prescribes based on reliable feedback information. In Figure 11 is shown a second embodiment of the present invention where display/alarm module 890 replaces the rear electronic access cover 200. This miniaturized module 890 attached to device 100 as was similarly disclosed in Figure 6b utilizing screws 670 and threaded holes 630. The LCD (liquid crystal display) 1135 and push-bottoms 1110 and 1120 are interconnected to microprocessor 605(connections not shown) conventionally and respond to diverse program routines. One example of such routine is when the user would depress menu selection push-button 1110 until desired option appears in the display 1135, for example(NUMBER OF DOSAGES REMAINING). The user would then depress activate request push button 1120 for the response to the request, for example (150 DOSAGES UNTIL EMPTY) message 1130.The device 100 could know this information if it were programmed with the typical number of metered dosages as is purported by the medication manufacturer. Else the display would simply indicate, for example, (50 DOSAGES USED THIS CANISTER) as a message 1130. It is expressly understood that the type and meaning of messages 1130 and alarms 1131 indicated and displayed by module 890 is as varied as medications and concerns that doctors may have, and that the present invention contemplates, and is suited to deliver fully, utilization to satisfy the need.

In operation, the present invention device 100, being miniaturized, portable and having a familiar body housing 120 to users as non electronic medication inhaler dispensers,the user would install a conventional medication canister 215 in opening 130 for the dispensing of medication. Proximity reed switch 505 senses the canister being present in systemand event is logged in non-volatile memory 860. As user desires a dose of medication, device 100(which fits easily in palm of hand) is placed in front of user's face as Figure 1 shows in orientation, with mouthpiece 150 positioned such within that user's lips are around surface 305 so as to have opening 140 directly accessible to user's inner mouth and throat. The user would place forefinger of hand holding the device 100 in area 218 of the canister and press conventionally downward, (approximately 1/8 inch) to release one metered dose of medication from canister 215. Valve stem 220 actuates the release as is seated snugly in medication inlet 210. Fast response temperature thermistor 425, being substantially in the path of inhalant flow within sensing chamber 510, experiences a rapid drop of temperature with respect to quiescent temperature just previous to actuation of valve 220. The physical time of actuation inhalant release is typically 200 milliseconds. At the leading edge of the previous process,the microprocessor 605 has been initialized and latched operation power via electronic switch 845. Validation of signals generated by differentiating amplifier 820 and comparator 825 is processed together with 855 A/D converter signals to determine the positive medication inhalant release, and its strength with respect to magnitude and duration. Air flow thermistor 435 monitors the ambient air inlet 316 which allows air flow into the area of the inhalant sensing chamber 510 caused by the user's inhalation. The released medication and ambient air mix expands within chamber 310 area indicated by dotted lines 520 and is expelled out of mouthpiece opening 140. An important feature of the present

invention is expressly understood that the user is identified as positively inhaling the medication by the device 100 as prescribed (as opposed to simple being dispensed). This is defined as the medication being administered into the user's mouth, throat and respiratory system as intended. For example, actuation of the device 100 to test the function of the medication canister 215 without having mouthpiece within user's lips, would expel the medication into surrounding atmosphere. The fast response sensors 425 and 435 would produce different wave form characteristics then those disclosed in referenced time 880 and on A/D signals of lines 821 and 887 of Figure 8. This is possible by the distinct signature developed by the user drawing ambient air through inlet 316 and inhalant expanding within area 520 before being expelled. Thus, if accidental actuation, or misuse of device 100 occurs, appropriate event recording is chronologged and further complete positive analysis is possible by the prescribing doctor.

While the invention has been particularly shown, described and illustrated in detail with reference to the preferred embodiments and modifications thereof, it should be understood by those skilled in the art that equivalent changes in form and detail may be made therein without departing from the true spirit and scope of the invention as claimed, except as precluded by the prior art.

CLAIMS

1. A medication inhalant device adapted for receiving a conventional pressurized inhalant package therein and for dispensing a prescribed dosage of medication inhalant through the lips and into the mouth, throat, and respiratory system of a user of the device, the device comprising:

a mouthpiece for receiving the outlet of the inhalant package therein, the user's lips received around a portion of the exterior of said mouthpiece when dispensing the inhalant through the outlet, said mouthpiece having an air inlet therein;

first sensing means for sensing the release of the inhalant from the inhalant package, said first sensing means mounted inside said mouthpiece and adjacent the outlet of the inhalant package and in a path of flow of the inhalant dispensed from the inhalant package; and

a first signal generating means for determining when the inhalant is dispensed, said first signal generating means connected to said first sensing means and to a display means for displaying each occurrence of the release of the inhalant.

2. The device as described in claim 1 further including second sensing means for sensing the amount of air flow from said air inlet received in said mouthpiece, said second sensing means disposed adjacent said air inlet inside said mouthpiece and a second signal generating means for determining when the air flow is received in said mouth piece when dispensing the inhalant, said second signal generating means connected to said second sensing means and to said display means.

3. The device as described in claim 2 further including a package sensing means disposed on said mouthpiece for sensing when the outlet of the inhalant package is received and removed from said mouthpiece, said package sensing means connected to said display means.

4. The device as described in claim 3 further including computing and recording means for logging positively when the inhalant is dispensed, when the air flow is received in said mouthpiece when the inhalant is dispensed, and when the inhalant package is received and removed.

5. A medication inhalant device adapted for receiving a conventional pressurized inhalant package therein and for dispensing a prescribed dosage of medication inhalant through the lips and into the mouth, throat, and respiratory system of a user of the device, the device used for recording electronically the amount and duration of each dosage of medication dispensed from an outlet of the inhalant package, the device comprising:

a hand held housing having an open upper package receiving chamber for slidably receiving and holding the inhalant package therein and a lower chamber, the housing including an air inlet therein;

a mouthpiece extending outwardly from the lower chamber of said housing, the user's lips received around a portion of said mouthpiece when dispensing the medication;

first sensing means for sensing the release of the inhalant from the inhalant package, said first sensing means mounted inside said housing and adjacent the outlet of the inhalant package and in a path of flow of the inhalant dispensed from the inhalant package; and

a first signal generating means for determining when the inhalant is dispensed, said first signal generating means connected to said first sensing means and to computing and recording means for logging when the inhalant is dispensed.

6. The device as described in claim 5 further including second sensing means for sensing the amount of air flow received in the lower chamber, said second sensing means mounted inside said housing and adjacent said air inlet inside said housing and a second signal generating means for determining when air flow is received

in the lower chamber when dispensing the inhalant, said second signal generating means connected to said second sensing means and to said computing and recording means for logging when the air flow is received in the lower chamber when dispensing the inhalant.

7. The device as described in claim 5 further including a package sensing means disposed in said housing for sensing when the inhalant package is received in said housing and removed from said housing, said package sensing means connected to said computing and recording means for logging when the inhalant package is received and removed.

8. The device as described in claim 5 wherein said mouthpiece is a removable mouthpiece slidably received inside the lower chamber of said housing, the user's lips received around a portion of an exterior circumference of said removable mouthpiece when dispensing the medication.

9. The device as described in claim 5 further including programmable display means for displaying the number of dosages taken, the number of dosages remaining in the inhalant package, amount of each dosage dispensed from the inhalant package, the amount of air flow received in said mouthpiece and mixed with the dosage, and like data, said display means connected to said computing and recording means.

10. The device as described in claim 5 further including a remote retrieval and data processing means electrically connected to said computing and recording means for retrieval of chronology stored data such as amount and duration of dosages of medication positively dispensed over a period of time and patient related data for analysis by a doctor.

11. A medication inhalant device adapted for receiving a conventional pressurized inhalant package therein and for dispensing a prescribed dosage of medication inhalant through the lips and into the mouth, throat, and respiratory system of a user of the device, the device used for recording electronically the amount

and duration of each dosage of medication dispensed from an outlet of the inhalant package, the device comprising:

a hand held housing having an open upper package receiving chamber for slidably receiving and holding the inhalant package therein and a lower chamber, the housing including an air inlet therein;

a mouthpiece extending outwardly from the lower chamber of said housing, the user's lips received around a portion of said mouthpiece when dispensing the medication, the outlet of the inhalant package received in a spray orifice inside said mouthpiece;

first sensing means for sensing the amount and duration of inhalant released from the inhalant package, said first sensing means mounted inside said housing and adjacent the outlet of the inhalant package disposed inside said mouthpiece and in a path of flow of the inhalant dispensed from said spray orifice;

a first signal generating means for determining the amount and duration of the inhalant dispensed, said first signal generating means connected to said first sensing means and to computing and recording means for positively logging the amount and duration of the inhalant dispensed, said computing and recording means packaged inside a portion of said housing;

second sensing means for sensing the amount of air flow received in the lower chamber and through said mouthpiece, said second sensing means mounted inside said housing and adjacent said air inlet inside said housing; and

a second signal generating means for determining the amount and duration of air flow received in the lower chamber and through said mouthpiece when dispensing the inhalant, said second signal generating means connected to said second sensing means and to said computing and recording means for logging the amount of air flow received in the lower chamber and through said mouthpiece when dispensing the inhalant.

12. The device as described in claim 11 further including an electronically operated switch disposed in the upper chamber of said housing for sensing when the inhalant package is received therein and removed therefrom, said switch connected to said computing and recording means for logging when the inhalant package is received and removed.

13. The device as described in claim 11 wherein said mouthpiece is a removable mouthpiece slidably received inside the lower chamber of said housing, the user's lips received around a portion of an exterior circumference of said mouthpiece when dispensing the medication.

14. The device as described in claim 11 further including display means mounted on a portion of an exterior of said housing for displaying the number of dosages dispensed from the inhalant package, the number of dosages remaining in the inhalant package and the like, said display means connected to said computing and recording means.

15. The device as described in claim 11 wherein said first sensing means is a fast response temperature thermistor mounted inside said housing and adjacent the outlet of the inhalant package and in the path of flow of the inhalant dispensed from the inhalant package for sensing the amount and duration of inhalant released from the inhalant package.

16. The device as described in claim 15 wherein said fast response temperature thermistor senses the temperature change caused by the expansion of the medication inhalant as it exits the outlet of the inhalant package and enters into the air flow in said mouthpiece.

17. The device as described in claim 15 wherein said fast response temperature thermistor is received inside the spray orifice of said mouthpiece and adjacent the outlet of the inhalant package.

18. The device as described in claim 17 wherein the inhalant package is a pressurized canister having a valve stem for releasing the inhalant, the valve stem received inside the spray orifice of said mouthpiece and adjacent an end of said fast response temperature thermistor.

19. The device as described in claim 11 wherein said second sensing means is an ambient air flow thermistor mounted inside said housing and adjacent the air inlet inside said housing for sensing the amount of air flow received in the lower chamber.

20. The device as described in claim 19 wherein said air inlet has a fixed cross sectional area for providing adequate air flow and is disposed between the open upper chamber and the lower chamber of said housing.

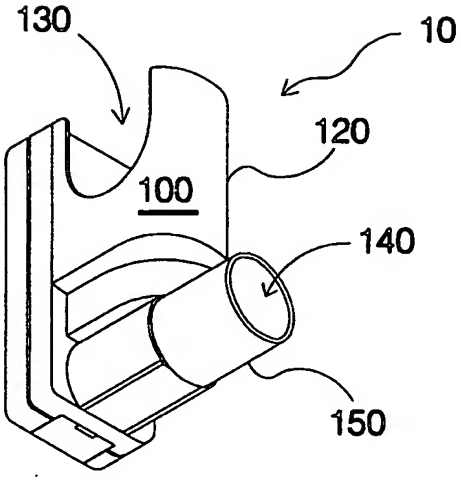


FIGURE 1

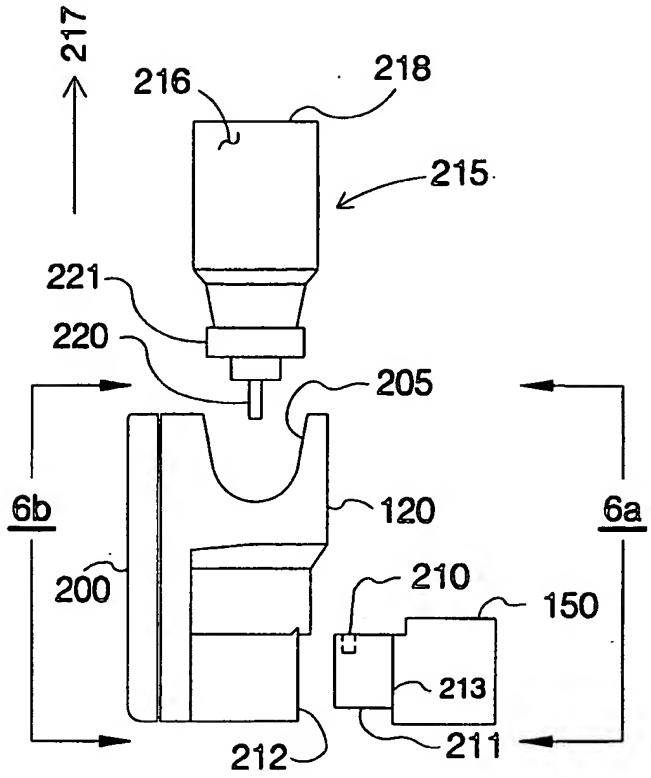


FIGURE 2

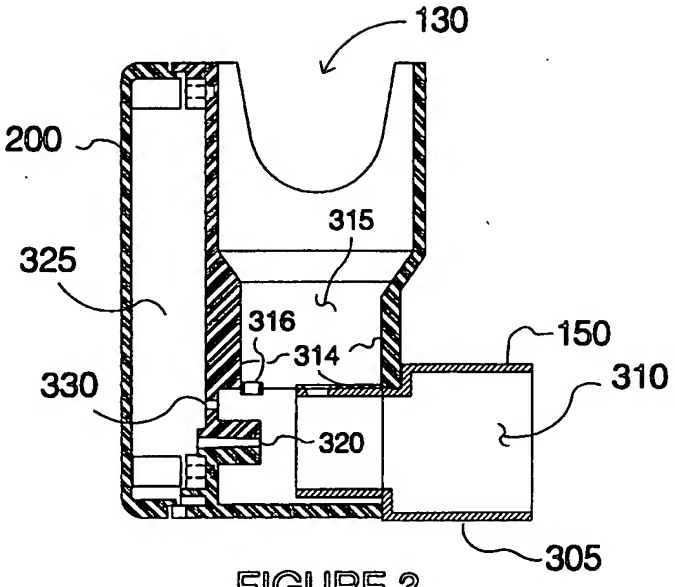


FIGURE 3

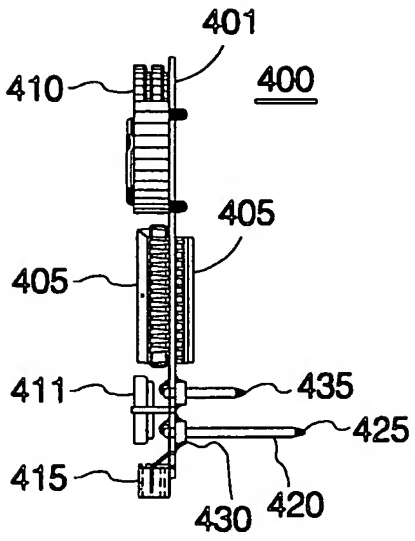


FIGURE 4

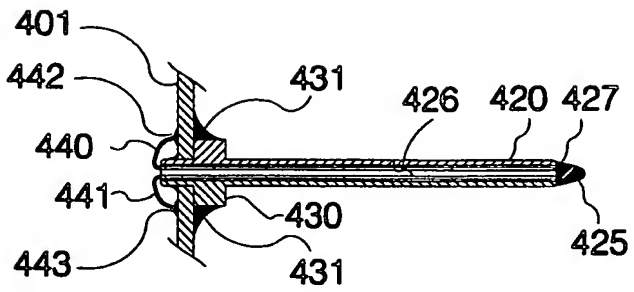


FIGURE 4a

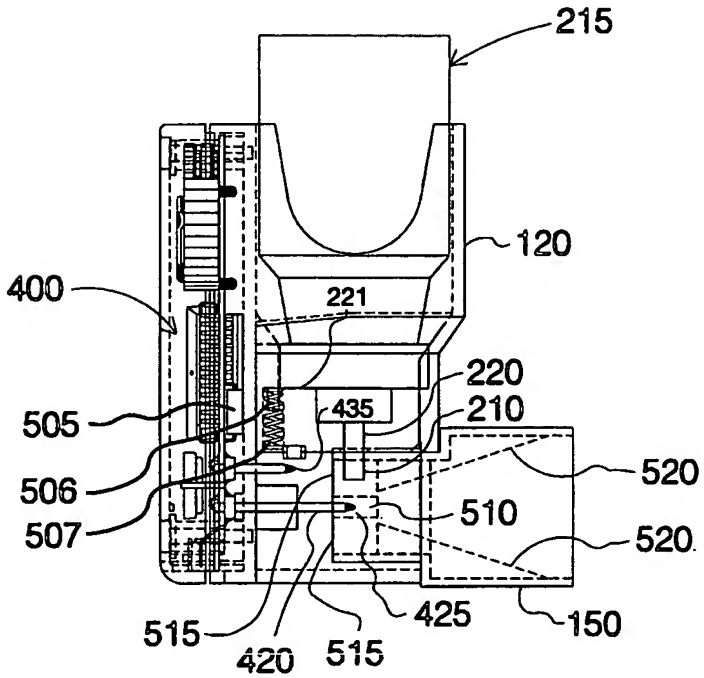


FIGURE 5

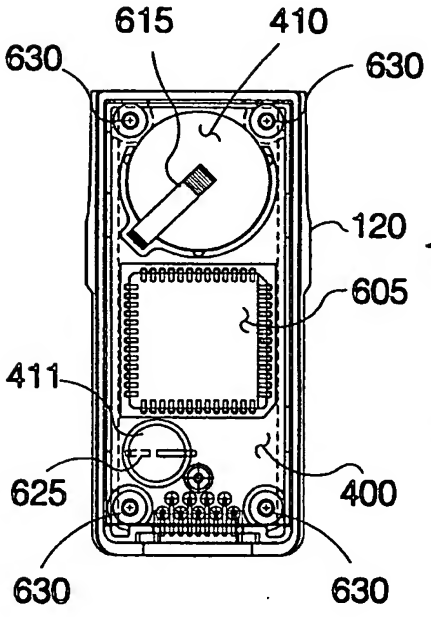


FIGURE 6

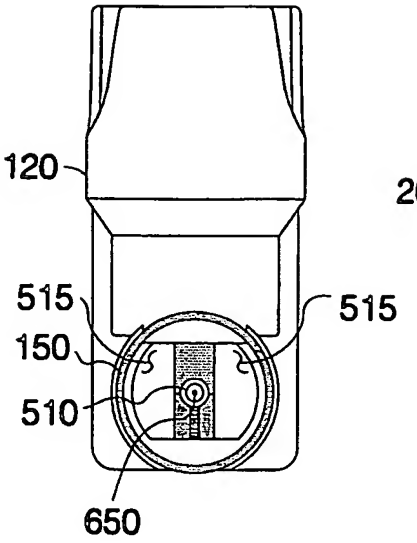


FIGURE 6a

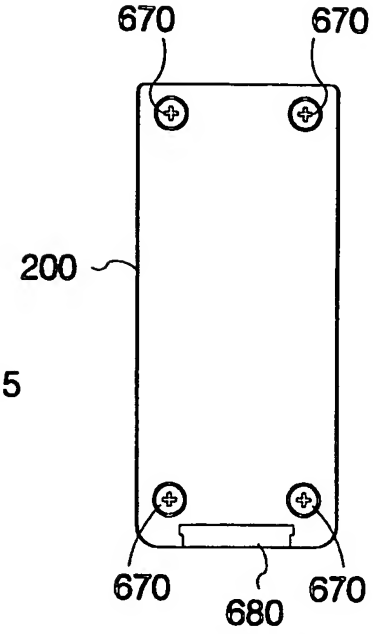


FIGURE 6b

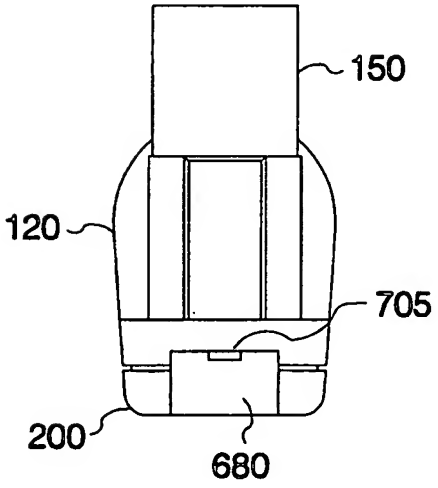


FIGURE 7

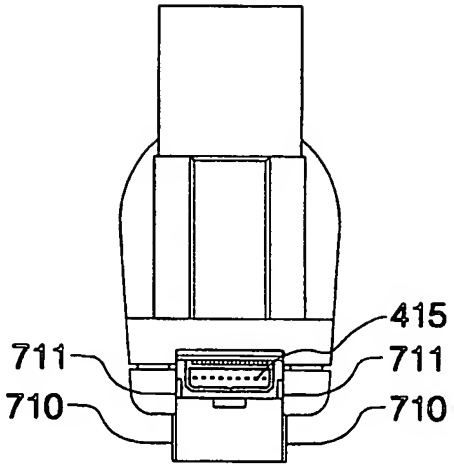


FIGURE 7a

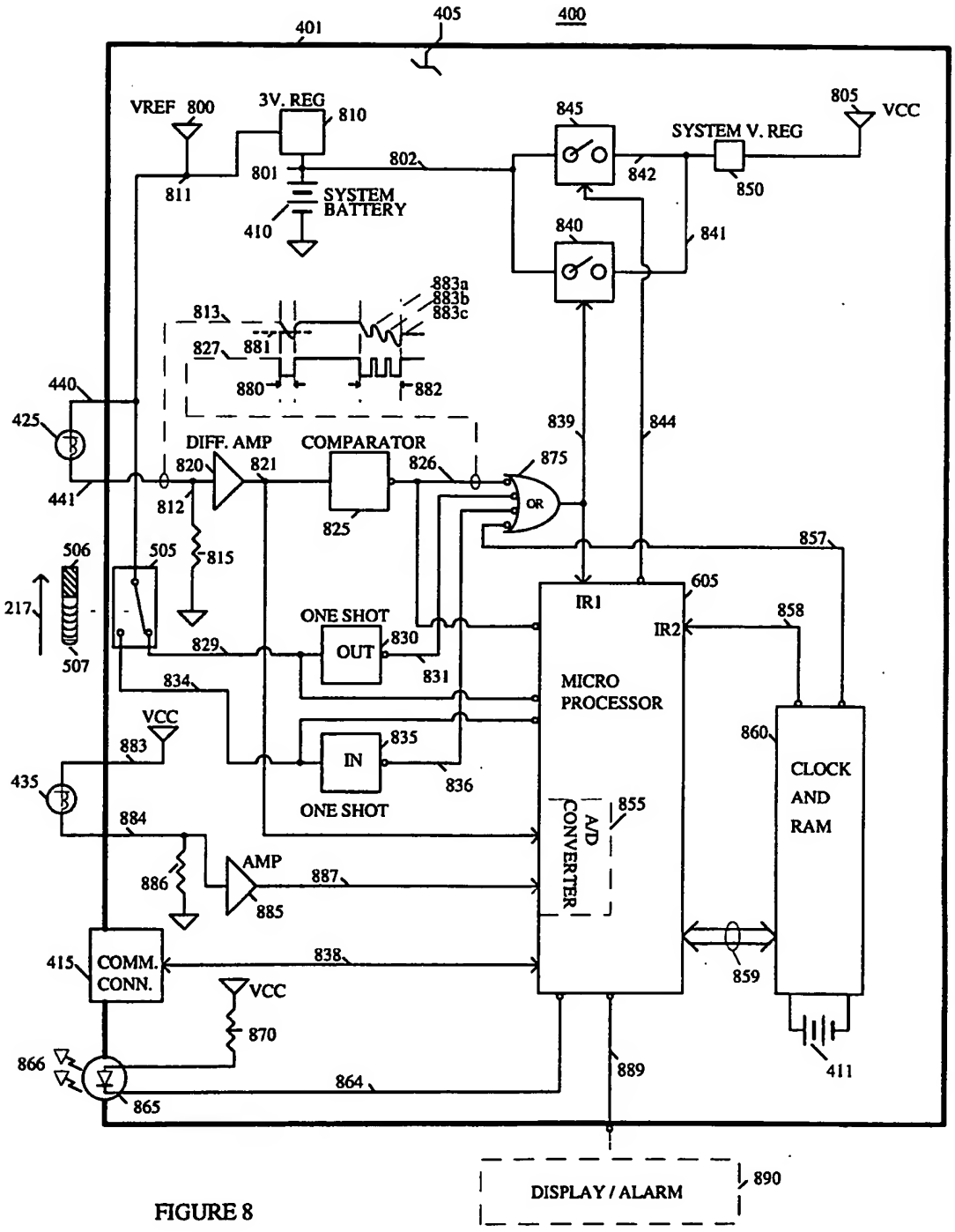

401
405
400
VREF 800
3V. REG
810
811
801
802
SYSTEM BATTERY
410
845
842
SYSTEM V. REG
805
VCC
850
840
841
883a
883b
883c
813
827
881
880
882
440
425
441
DIFF. AMP
820
821
812
COMPARATOR
826
825
875
OR
839
844
857
506
505
815
217
507
ONE SHOT
OUT
829
830
831
605
IR1
IR2
858
MICRO PROCESSOR
834
VCC
883
IN
835
836
ONE SHOT
435
884
886
AMP
887
885
855
A/D CONVERTER
860
CLOCK AND RAM
415
COMM. CONN.
838
VCC
870
859
866
865
864
889
411
DISPLAY / ALARM
890

FIGURE 8

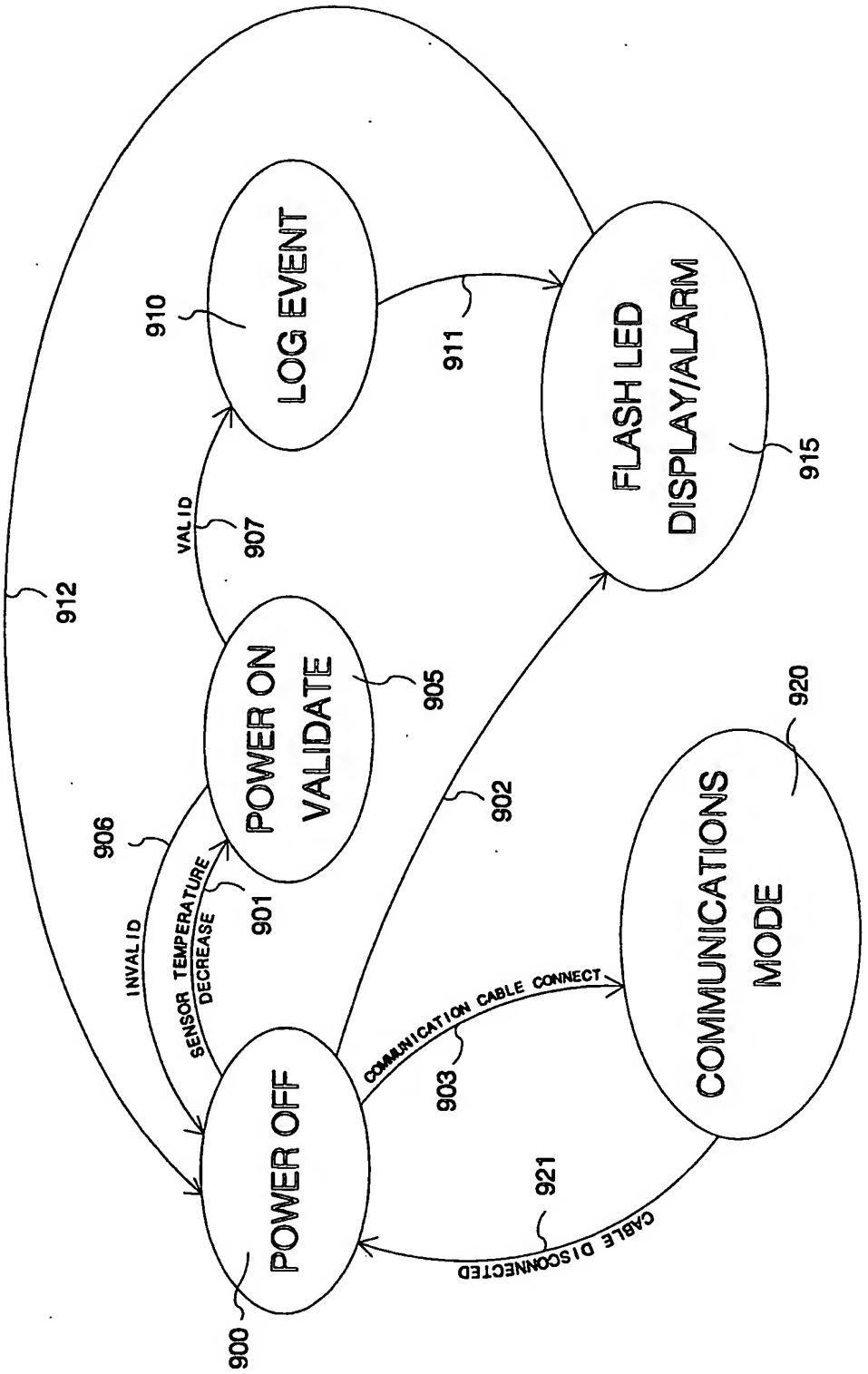


FIG 9

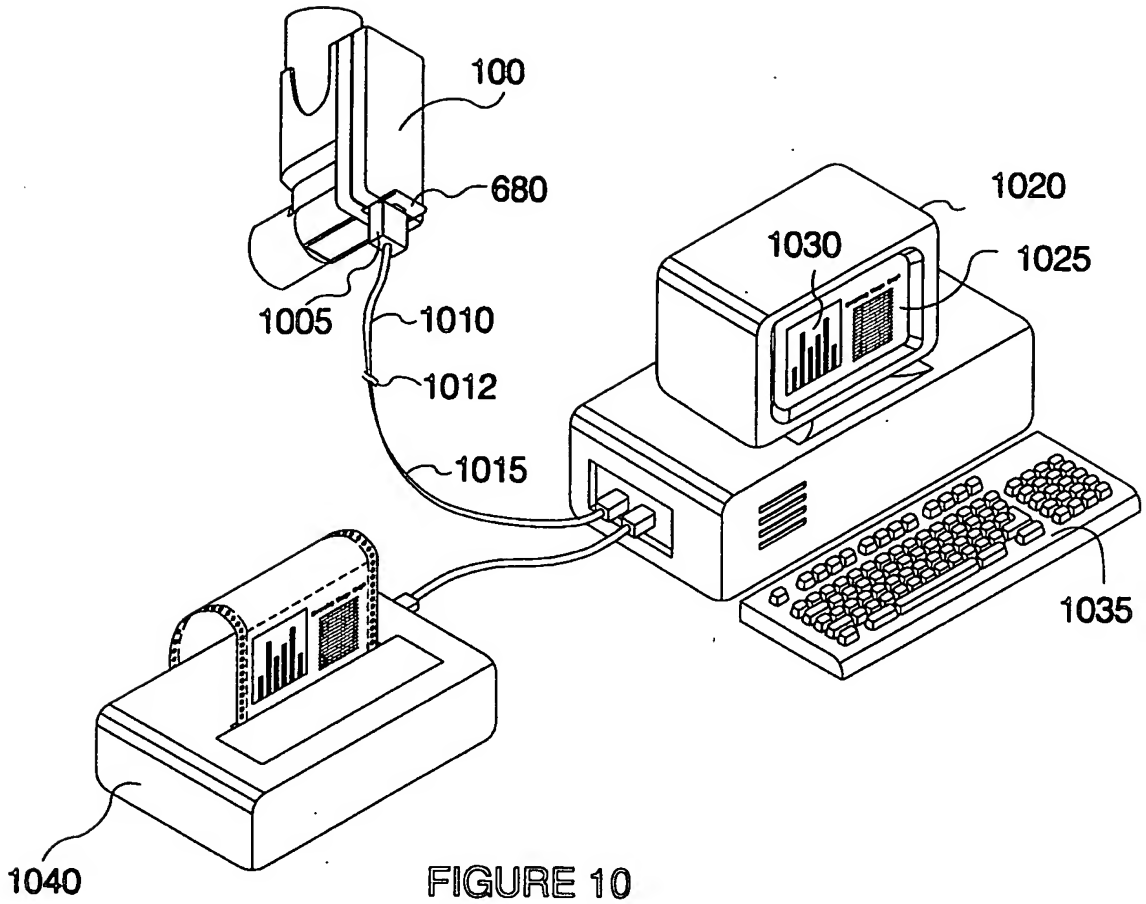


FIGURE 10

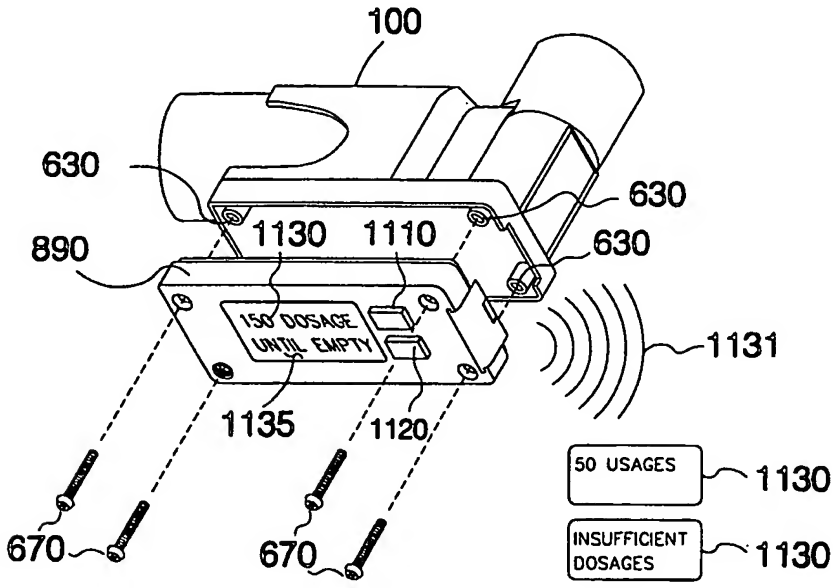


FIGURE 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/10310

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 11/00, 15/00, 16/00; B05D 7/14; B65D 83/06
US CL :128/200.14, 200.23, 203.12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/200.14, 200.23, 202.22, 203.12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---, P Y	US, A, 5,284,133 (BURNS ET AL), 08 February 1994. See the entire document.	1, 5, 10 --- 2-4, 6-9, 11-20
Y	US, A, 4984158, (HILLSMAN), 08 January 1991. See the entire document.	2-4, 6-9, 11-20
Y	WO, A, 92/17231, (HAVER ET AL), 15 October 1992. See the entire document.	3, 4, 7-9, 12, 13

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be part of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 NOVEMBER 1994	17 JAN 1995

Name and mailing address of the ISA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	KIMBERLY LYNN ASHER
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0332

Form PCT/ISA/210 (second sheet)(July 1992)★